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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/615,659 | 07/09/2003 | John N. Feder | D0283 NP | 6678 |

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| EXAMINER | |
|---|---|
| MONSHIPOURI, MARYAM | |
| **ART UNIT** | **PAPER NUMBER** |
| 1653 | |

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/615,659 | FEDER ET AL. | |
| | Examiner | Art Unit | |
| | Maryam Monshipouri | 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *21-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *21-29,44,45 and 47-52* is/are allowed.

6)☒ Claim(s) *3043, 46, 53-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *filed 9/05& 1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's response to restriction requirement filed 9/1/2005 is acknowledged. Applicant elected Group I invention, directed to DNA sequences encoding testis specific tyrosine like protein (BGS42) without traverse. Claims 1-20 are canceled. Claims 22-55 are under examination on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "does not hybridize under stringent conditions to a nucleic acid molecule having a nucleotide sequence of only A residues or of only T residues" is unclear. It is unclear whether applicant is referring to a nucleic acid that is completely made up of A or T residues or other residues should also be present. Appropriate clarification is required.

Claims 45-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "CpG island regions" in claim 45 and 46 is unclear.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "a polynucleotide that is at least 80% identical to

amino acids 2-541" is unclear. It is unclear as how a polynucleotide should have identity to a polypeptide.

Claims 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "at least one nucleotide within the CpG island regions encompassed by nucleotides ..." is unclear. How could one nucleotide be encompassed by many? Also, the entire claim 45 does not make grammatical sense. Appropriate correction is required.

Claims 30-31 recite the limitation "claims 30 refers back to said heterogonous nucleic acid sequence as a limitation. There is insufficient antecedent basis for this limitation in the claim. Similarly claim 31 refers to said heterogonous polypeptide and there is insufficient antecedent basis for said limitation.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-35, 39-43 and 53-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleic acids encoding BGS42, does not reasonably provide enablement for any of the following:

**(a)** isolated DNA sequences comprising polynucleotides having 80% identity to those encoding residues 1-541 or 2-541 of SEQ ID NO:2, with no function.

**(b)** isolated DNA sequences encoding a polypeptide comprising 50 or 394 contiguous amino acids of SEQ ID NO:2 with no function.

**(c)** isolated nucleic acid molecules comprising 150 contiguous nucleotides of SEQ ID NO:1, with no function.

**(d)** isolated DNA sequences comprising residues 369-1247 and 549-1274 of SEQ ID NO:1 or encoding residues 73-365 of SEQ ID NO:2, with no function.

**(e)** an isolated polynucleotide that hybridizes to that encoding residues1-541 or 2-541 of SEQ ID NO:2, under stringent conditions recited in claim 55, and wherein said polynuclotide does not hybridize to a nucleotide sequence of only A or T residues (see claim 55) , with no function.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The specification fails to teach which residues within the claimed DNA sequences should remain intact such that said products listed as (a)-(e) above retain their function. No examples of such critical residues are provided either. Current state of the art indicates that once more than 3-9 residues of a polynucleotide encoding a full-length polypeptide is simultaneously mutated (see parts (a) and (e) above) or once most of the structure of a polynucleotide encoding a full-length polypeptide is mutated such that it only needs to either encode a product comprising 50 or 394 residues of a full-

length polypeitde (see part (b)) or needs to merely comprise a region encoding fragments of said full-length polypeptide (see parts (c)-(d)), said product is not necessarily capable of encoding products with the same activity as said full-length polypeptide.

Therefore due to lack of sufficient guidance and examples provided in the specification and due to unpredictability of prior art as to which residues within the polynucleotides of parts (a)-(e) above should be retained such that said products encode products with tyrosine ligase activity one of skill in the art has to go through the burden of undue experimentation in order to screen for those products that are within he scope of this invention and as such the claims go beyond the scope of the disclosure.

Claims 32-35, 36-38 , 39-43, 53-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 32-35, 39-43 and 53-54 are directed to a genera of polynucleotides that have been inadequately described in the specification:

**(a) a genus** of isolated DNA sequences comprising polynucleotide having 80% identity to those encoding residues 1-541 or 2-541 of SEQ ID NO:2, with no function.

**(b) a genus** of isolated DNA sequences encoding a polypeptide comprising 50 or 394 contiguous amino acids of SEQ ID NO:2 with no function.

**(c) a genus** of isolated nucleic acid molecules comprising 150 contiguous nucleotides of SEQ ID NO:1, with no function.

**(d) a genus** of isolated DNA sequences comprising residues 369-1247 and 549-1274 of SEQ ID NO:1 or encoding residues 73-365 of SEQ ID NO:2, with no function.

**(e) a genus of** isolated polynucleotides that hybridize to that encoding residues either 1-541 or 2-541 of SEQ ID NO:2, under stringent conditions recited in claim 55, and wherein said polynuclotides do not hybridize to a nucleotide sequence of only A or T residues (see claim 55) , with no function.

The specification does not contain any disclosure of the function of all DNA sequences that are listed in sections (a)-(e) above. The genus of cDNAs that comprise these above cDNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a **single species** (namely poluynucleotides encoding SEQ ID NO:2) of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

With respect to claims 36-38, It is noted that the applicants have deposited the organisms under the terms of Budapest treaty but there is no indication in the specification as to the public availability. Since the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

Claims 39-40, 45-46, 53-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner searched the specification for the support of isolated nucleic acid molecules encoding SEQ ID NO:2 attached to mutants (including deletion mutants) of a specific promoter set forth as SEQ ID NO:27 in the regions indicated in claims 45-46 as well support for the subject matter of claims 53-54, 39-40 and could not find any. Hence, for examination purposes said claims are considered to be **New Matter**. Applicant is advised to either refer the examiner to the places in the specification wherein support for said claims are provided or possibly delete said claims.

***Allowable Subject Matter***

21-29, 44-45, 47-52 are allowed. This because polynucleotides encoding SEQ ID NO:2 or specifically claimed fragments thereof, and polynucleotides set forth as SEQ ID NO:27 and specifically claimed fragments thereof are free of prior art. Further, the prior art does not teach or suggest preparing such specifically claimed products. Hence said products are also non-obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber Jon P. can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Monshi

Maryam Monshipouri Ph.D.

Primary Examiner